Special 510(k) Submission
TruePath™ CTO Device

APR 1 6 2014

510(k) Summary

per 21 CFR §807.92

Submitter's Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Carol Tiffany Senior Regulatory Affairs Specialist Phone: 763-494-1106 Fax: 763-494-2222 e-mail: carol.tiffany@bsci.com
Date Prepared	04 February 2014
Proprietary Name	TruePath™ CTO Device
Common Name	CTO Device
Product Code	PDU – Catheter for Crossing Total Occlusions
Classification	Class II, 21 CFR Part 870.1250 – Percutaneous Catheter
Predicate Device(s)	ReVascular Therapies Chronic Total Occlusion (RVT CTO) Device (marketed as TruePath CTO Device) K101599 18 January 2011
Device Description	The TruePath CTO Device is a sterile, disposable, steerable, 0.018" OD Guidewire with an Active Tip for penetrating chronic total occlusions and is used with a sterile, disposable battery-operated Control Unit during a single patient procedure. The TruePath CTO system consists of the TruePath CTO Device, Control Unit, Shaping Tool, and the TruePath Extension Wire. The TruePath CTO Device consists of a distal 0.018"guidewire assembly and a Motor Housing with a Connector Cable to the Control Unit. The TruePath CTO Device has a 165 cm working length with a hydrophilic coating. The distal tip is shapeable and the cone shaped portion is diamond coated. The distal 3 cm of the guidewire is radiopaque. The Control Unit, when activated, allows current to flow to the motor to turn the driveshaft, located within the stationary hollow outer shaft. The active tip at the most distal end of the guidewire assembly rotates at approximately 13,000 RPMs under no load conditions. In active mode the TruePath guidewire assembly creates a pathway through the lesion via mechanical rotation. In the passive mode the guidewire assembly functions as guidewire. The shaping tool is an accessory provided with the TruePath CTO Device to shape the tip if desired. The TruePath Extension Wire can be attached to the TruePath guidewire assembly to create an extended guidewire that can be used to exchange a catheter without moving the TruePath CTO Device from the artery.

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Intended Use/Indications for Use

The TruePath CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.
The device is contraindicated for use in carotid arteries.

The TruePath Extension Wire is designed to extend the TruePath CTO Device so that a catheter can be exchanged for another catheter.

Comparison of Technological Characteristics

The TruePath CTO Device incorporates substantially equivalent device materials, device configuration, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate device.

Comparison to Predicate Device:

Characteristic	Proposed compared to Predicate
Mechanism of Action	Same Mechanism of Action
Components	Same components, configuration, design and function. Two additional components to the motor housing.
Materials	Same with exception of the motor housing components.
Packaging	Same packaging materials and configuration.
Sterilization Method/SAL	Same method and level of assurance.
Device Compatibility	Same compatibility.
Device Dimensions	Same dimensions.
Effective Length	Same length device.
Radiopacity	Same radiopacity.
Biocompatibility	Same biocompatibility.

Performance Data

Bench testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following in-vitro performance tests were completed:

Effective Length	Baseline Motor Current
Distal Shroud Detachment	Motor Housing Detachment
Run Life II (operating at normal resistance)	Run Life III (operating at increased resistance)

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the TruePath CTO Device has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the RVT (TruePath) CTO Device as submitted in K101599.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Boston Scientific, Inc.
c/o Ms. Carol Tiffany
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K140288
Trade/Device Name: TruePath™ CTO Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: March 18, 2014
Received: March 19, 2014

Dear Ms. Tiffany:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: TruePath™ CTO Device

Indications for Use:

The TruePath CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.
Contraindications:
The device is contraindicated for use in carotid arteries.

The TruePath Extension Wire is designed to extend the TruePath CTO Device so that a catheter can be exchanged for another catheter.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S